REMARKS

Claims 1-19 are pending in the present application. Claims 5 and 13-18 have been withdrawn from consideration. Support for newly added claim 19 can be found in claim 5 and paragraph 19 which states that the application process can involve sequential application of therapeutic agents to different portions of the medical device with intermediate determinations of the actual amount of drug disposed on the medical device between the application steps.

Claims 1-4 and 6-12 are rejected under 35 U.S.C. §112 for allegedly lacking written description. Claims 1-4 and 6-12 are rejected under 35 U.S.C. §103(a) for being allegedly rendered obvious by U.S. Patent Publication No. 2002/0133183 to Lentz ("Lentz"). Applicants traverse these rejections.

Claims 1-4 and 6-12 Do Not Lack Written Description

According to the Examiner, claims 1-4 and 6-12 lack sufficient written description with respect to applying different therapeutic agents on the medical device. The Examiner believes that it is not clear how the amount of the first agent can be used to determine the amount of the second agent to be applied, if the second agent is different from the first agent. Specifically, the Examiner does not understand how the amount of drug X applied in the first coating can be used to determine how much of drug Y to apply in the second coating. Applicants submit that paragraph 11 of the specification clearly states that the first and second therapeutic agents can be the same or different compositions. Paragraph 12 states that the present invention provides a multi-step method of manufacturing a medical device containing a first and a second therapeutic agent that results in a lower maximum error in the total amount of the first and second therapeutic agent actually disposed on the medical device.

Therefore, if a total combined amount of drug X and drug Y are desired to be applied on the medical device, then the intermediate step of determining the amount of drug X actually disposed on the medical device, in accordance with claims 1-4 and 6-12, can be used to determine how much of drug Y is to be deposited on the medical device. For example, if it is desired to have 100 mg total of drug X and drug Y on the medical

device (and it is not desired to deposit any specific relative amounts of drug X and Y on the medical device), then the intermediate determination step, as described in paragraph 12 of the specification, is applicable whether the first and second therapeutic agent are the same or different. Specifically, if the first portion comprises 40% of the surface area of the medical device, then 40 mg of drug X can be applied to the first portion. If the intermediate determination step reveals that only 36 mg of drug X was actually deposited on the medical device, then a second amount of 64 mg of drug Y can be applied to provide a total amount of 100 mg of drug X and Y. If it is desired to deposit drug X and Y on the medical device in a specific ratio, then an intermediate determination step can be made after each drug application, as recited in new claim 19. Both of these approaches involving the application of different drugs are sufficiently described in the specification and particularly in paragraph 11, 12 and 19.

Claims 1-4 and 6-12 Are Not Rendered Obvious by Lentz

The Examiner acknowledges that Lentz does not directly state that the amount of heparin on the outer surface of the medical device is coordinated with the amount applied to the inner surface of the medical device. However, the Examiner states that it would have been obvious to one of ordinary skill in the art to have coordinated the amount of drugs applied to the two surfaces. Applicants take issue with this conclusion, since the Examiner has pointed to absolutely no rationale or teaching in the art or in Lentz that would motivate one skilled in the art to determine the actual amount of the drug applied to one surface of the medical device before applying drug to another surface of the medical device. There is no teaching in Lentz or any other reference described by the Examiner that even recognizes that there is a need to reduce the overall error rate in the application of a drug(s) to a medical device, let alone to reduce the overall error rate using the method recited in claims 1-4 and 6-12. For at least this reason, Applicants submit that claims 1-4 and 6-12 are not rendered obvious by Lentz and Applicants request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON

Date: 2-13-06

By: _____

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